CuztomGraft Solutions™
for Guided Bone Regeneration

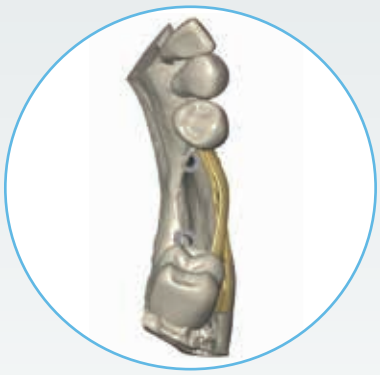
AccuraPlate™

ZimVie

AccuraPlate Products

CuztomGraft Solutions for Guided Bone Regeneration

The combined use of bone graft materials, barrier membranes and supportive materials has resulted in the development of different techniques to reconstruct hard-tissue defects prior to implant placement.[1-4] One of the techniques, the so-called plate or shell technique, describes the use of thin cortical plates harvested from the ramus together with autogenous bone particles to achieve horizontal and vertical bone gain.[5,6] Although this technique has shown proven long-term results, a second surgery to harvest autogenous bone is required, which leads to extended surgery time and increased morbidity.[6,7] A variety of options have been introduced to eliminate the need to harvest cortical bone plates such as synthetic or allograft materials.[8,9] However, a crucial surgery step is to shape the products chairside to fit the anatomical contour of the defect site.



ZimVie Dental AccuraPlate

PEEK AccuraPlate is designed using a fully digital workflow. Data from 3D medical imaging devices combined with modern Computer-Aided Design (CAD) software and state-of-the-art Computer-Aided Manufacturing (CAM) processes result in a high-quality customized medical device for guided bone regeneration procedures.[10] The use of PEEK AccuraPlates enables clinicians to benefit from the advantages of the plate technique accompanied by a precise fit and eliminates the need to shape the product chairside or to harvest autogenous bone from a second surgery site.[10]

Your Benefits

ZimVie Dental PEEK AccuraPlates have the following features:

1

Pre-Planned Fixation Screw Positions

- For reliable fixation
- Reduces the risk of touching sensitive anatomical structures[11]

2

Sterile Packaged – Ready for Use

- 10^{-6} Sterility Assurance level of [10]

3

Space Maintaining

- Protects and secures bone graft particulates for undisturbed healing[10]

4

Reduced Surgery Time and Morbidity

- Additional manual adjustment of the defect and of the PEEK AccuraPlate is seldom required, allowing for reduced surgery time and reduced morbidity[12]

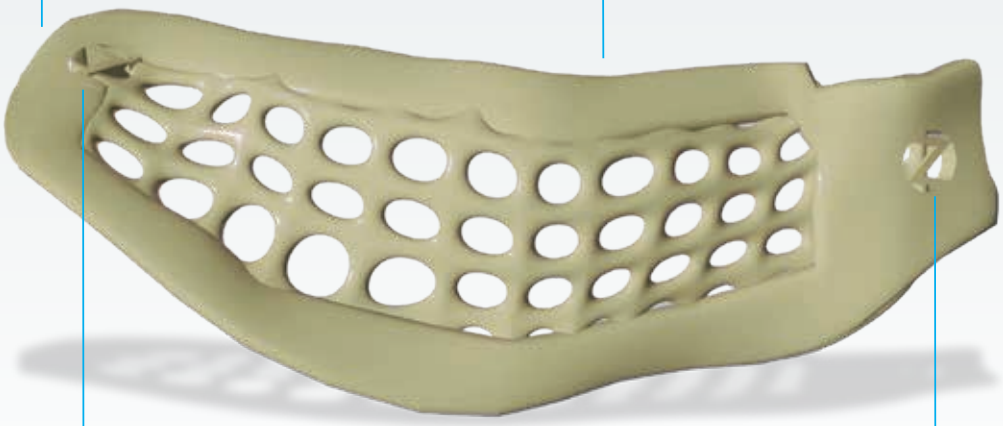
PEEK AccuraPlate: Product Features at a Glance

Made of Implantable Grade Polyether Ether Ketone Filament (PEEK) by Fused Deposition Modeling Technology

- Proven biocompatibility[13]
- Designed for long-term implantable medical devices[10]
- Residual metal ions acc. to ISO 10993-18 less than 0.5 ppm[13]

Smooth Surface

- For reduced bacterial adhesion[14]



Pre-Planned Screw Positions

- For reliable fixation

Please Note the Following Information

Imaging

Patient Preparation

- Remove temporaries and metal restorations, where possible
- Position patient in stable position

Imaging Requirements

- In general, most CT/CBCT devices are suitable
- Recommended slice thickness: 0.2 to 0.75 mm
- Gantry angle: 0°
- Open bite scan
- Please ensure that high-contrast imaging is achieved, particularly in the case of cancellous structures and thin residual bone (e.g. thin sinus floor).

Scan Data

- Do not use data compression
- Data must be provided in DICOM format only*
- Transfer the files using ZimVie Dental Upload website: **CuztomGraft.ZimVie.com**

Planning and Design

Design Draft

- You will receive by e-mail (I) a 3D-PDF file of the designed customized mesh and the defect site and (II) design & validation form
- To open the PDF files, Adobe Acrobat Reader is required
- Adjustments can be made at any time before final approval

Surgery

- Select proper flap design and soft-tissue management to ensure tension-free soft-tissue closure[15-18]
- Despite precise planning, the products may not fit as expected and minor manual adjustments may be required

Ordering Information

Item #	Description
PCPS	PEEK AccuraPlate Standard (up to 4 missing teeth)
PCPL	PEEK AccuraPlate Large (5 or more missing teeth)

AccuraPlate Products are class IIb medical devices.

* Please contact your radiologist or device manufacturer if you have any questions on DICOM export.

Design and Order Process

1. Data Submission

Fill in the product request form (online or using form ZV0587) and transfer together with CT/CBCT data (DICOM format required) using ZimVie Dental upload website: **CuztomGraft.ZimVie.com**

2. Design Phase

The AccuraPlate will be designed according to the requirements written on the request form, and you will receive an e-mail with a 3D-PDF file for review. Adjustments can be made to the design at any time prior to final approval.

3. Approval

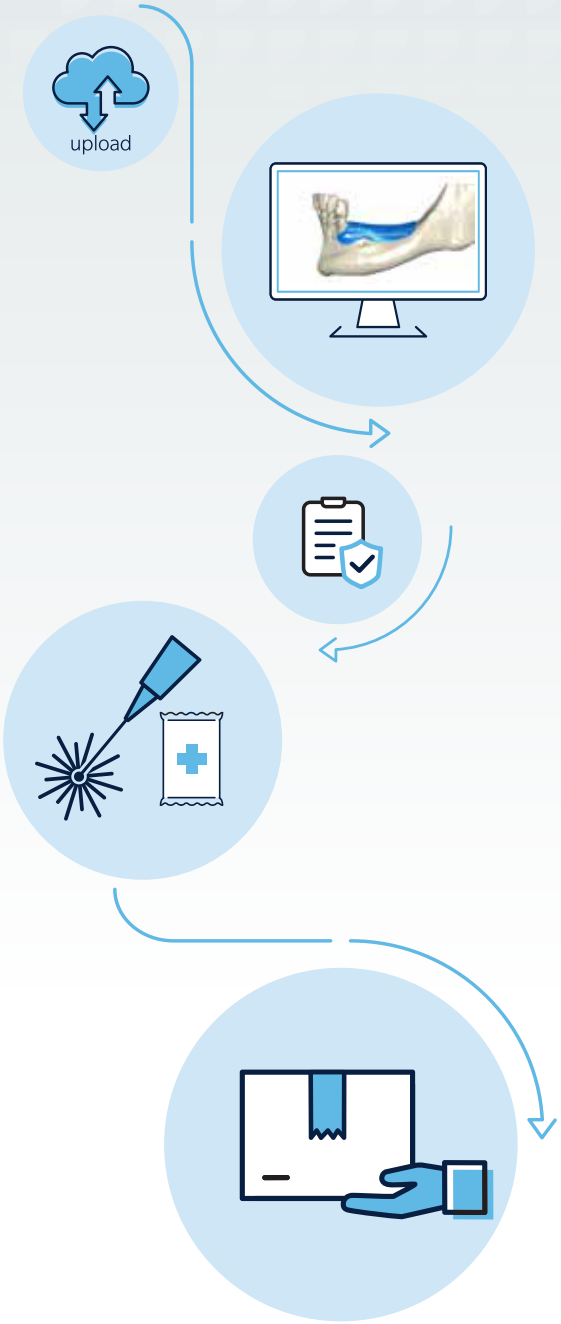
Once the design is finalized, your approval is required to release the mesh for manufacturing.

4. Manufacturing of the Plate

PEEK AccuraPlates are manufactured by Fused Deposition Modeling (FDM). The final products are ETO sterilized and provided in a blistered, sterile packaging.

5. Shipment

Once the final design has been approved (step 3), the AccuraPlate will be released from manufacturing after approximately two weeks. The expected delivery date will be confirmed to allow you to schedule surgery accordingly.



Clinical Case

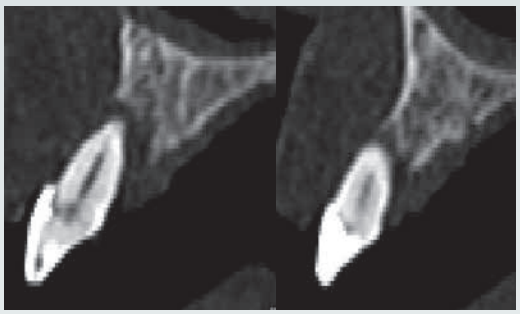


Fig. 1 Central and lateral incisor in the left maxilla with hopeless prognosis prior to extraction.

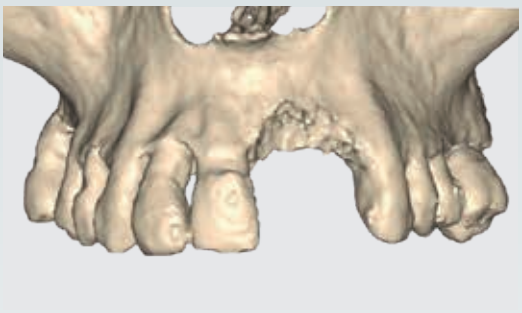


Fig. 2 3D rendering shows severe vertical bone defect.

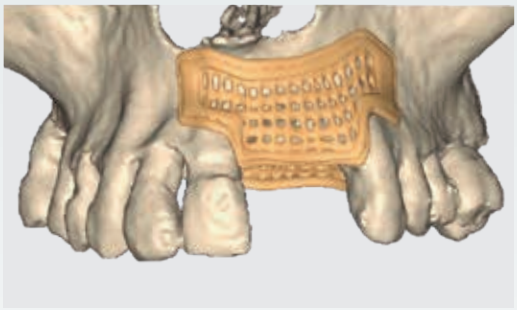


Fig. 3 Designed PEEK AccuraPlates (lateral view).

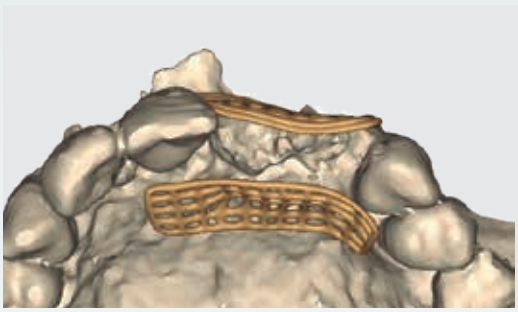


Fig. 4 Designed PEEK AccuraPlates (occlusal view).

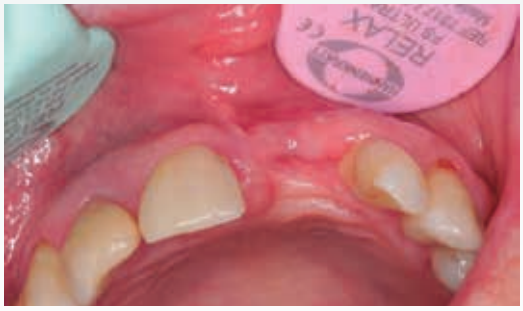


Fig. 5 Clinical situation after extraction and soft-tissue healing (occlusal view).

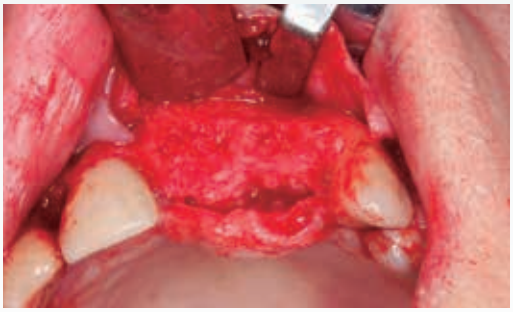


Fig. 6 Bone defect after raising a full thickness flap.

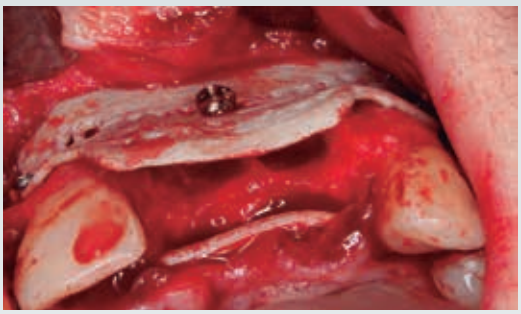


Fig. 7 PEEK AccuraPlates in place and fixed with screws.

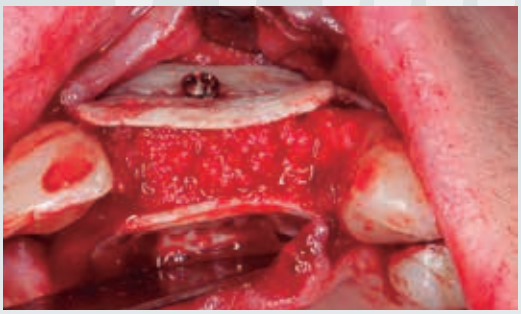


Fig. 8 Site grafted with 100% autogenous bone.

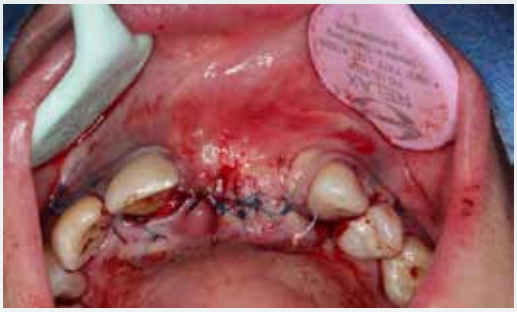


Fig. 9 Closed surgical site after grafting procedure.

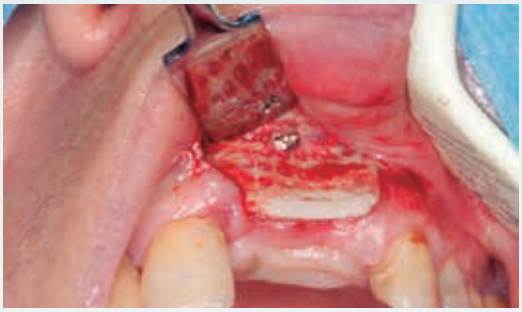


Fig. 10 Re-entry after 4 months healing time.

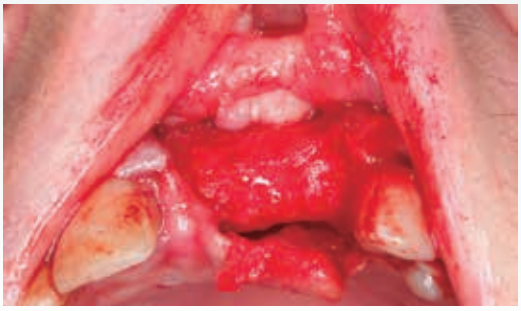


Fig. 11 Revascularized newly formed bone after plate removal.

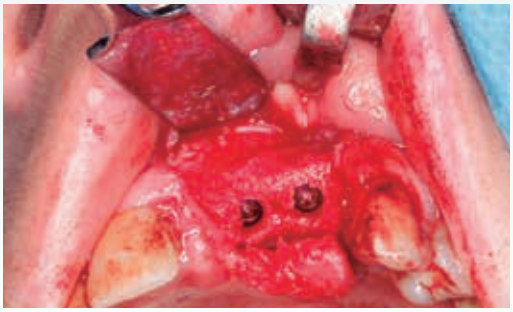


Fig. 12 Two implants have been placed with primary stability.

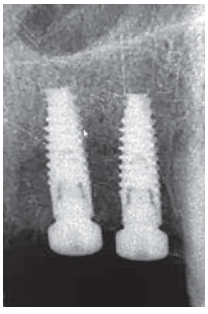


Fig. 13 Radiograph taken post-implantation shows regenerated hard-tissue around placed implants.

Clinical photographs courtesy of Dr. N. Cruz.
Individual results may vary.

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AccuraPlate products are class IIb medical devices.